

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

UCB BIOPHARMA SPRL,

Plaintiff,

v.

MEDIMMUNE, LLC,

Defendant.

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C.A. No. _____

COMPLAINT

Plaintiff UCB BioPharma SPRL (“UCB” or “Plaintiff”), by its undersigned attorneys, for its Complaint against Defendant MedImmune, LLC (“MedImmune” or “Defendant”) herein alleges:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from MedImmune’s infringement of United States Patent No. 7,566,771 (the “771 patent”) by its manufacture, use, sale, and/or offer for sale of, *inter alia*, Synagis®.

PARTIES

2. Plaintiff UCB BioPharma SPRL, is a corporation organized and existing under the laws of Belgium, with its principal place of business in Brussels, Belgium.

3. Upon information and belief, Defendant MedImmune is a limited liability company organized and existing under the laws of the State of Delaware with a principal place of business at One MedImmune Way, Gaithersburg, Maryland 20878.

JURISDICTION AND VENUE

4. This is a civil action for patent infringement arising under the Patent Laws of the United States, including, *inter alia*, 35 U.S.C. § 271.

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over MedImmune by virtue of its domicile and presence in the State of Delaware, such that it is “at home” in the State of Delaware. This Court further has personal jurisdiction over MedImmune due to, *inter alia*, its having previously consented to the jurisdiction of this Court and its having engaged in systematic and continuous contacts with the State of Delaware. MedImmune sells numerous drug products throughout the United States, including within this District. Such products include Synagis®.

7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

8. On July 28, 2009, the United States Patent and Trademark Office duly and legally issued the ’771 patent, entitled “Humanised Antibodies.” At the time of its issue, the ’771 patent was assigned to Celltech R&D Limited. Currently, UCB is the lawful owner of and holds all rights, title, and interest in the ’771 patent. A copy of the ’771 patent is attached hereto as **Exhibit A.**

SYNAGIS®

9. MedImmune holds Biologics License Application No. 103770 for palivizumab, an antibody comprising the product that MedImmune sells under the trade name Synagis®. Synagis® is supplied in single-dose liquid solution vials containing 50 mg palivizumab per 0.5 mL or 100 mg palivizumab per 1 mL and is administered via intramuscular injection. The

Food and Drug Administration (“FDA”) first approved Synagis® for sale within the United States on June 19, 1998.

10. Palivizumab is a humanized antibody produced by recombinant DNA technology. Palivizumab is composed of two heavy-chains and two light-chains and has a molecular weight of approximately 148,000 Daltons. Palivizumab’s heavy chain derives from the constant domain of a human IgG1 antibody and the variable framework regions of the human Cor and Cess genes. As a humanized antibody, palivizumab includes non-human amino acid residues grafted into the human heavy chain variable region; these non-human amino acid residues derive from, *i.e.*, correspond to, the murine monoclonal antibody, Mab 1129.

11. Palivizumab specifically binds, with high affinity, to the F protein of respiratory syncytial virus (“RSV”).

12. MedImmune has sold and continues to sell Synagis® throughout the United States, including in this District.

13. MedImmune has manufactured and continues to manufacture palivizumab in the United States for distribution and sale throughout the world.

LICENSE AGREEMENT

14. On or around January 19, 1998, Celltech Therapeutics Limited (“Celltech Therapeutics”), a predecessor in interest of Celltech R&D Limited, entered into a licensing agreement with MedImmune, Inc., a predecessor in interest of Defendant MedImmune (the “License”). Under the License, Celltech Therapeutics granted MedImmune, Inc., a non-exclusive license to certain patents concerning humanized antibody technology including, *inter alia*, all patents issuing from divisions and/or continuations of United States Application No. 08/303,569 (the “’569 application”). The ’771 patent issued from United States Application No. 08/485,686, a continuation of the ’569 application.

15. As consideration for the license, MedImmune, Inc., agreed to pay Celltech Therapeutics certain royalties based on sales of products that fell within the scope of any licensed patent.

16. On or around June 24, 2005, Celltech R&D Limited (a successor in interest of Celltech Therapeutics) and MedImmune, Inc., amended the License. The modification did not affect the scope of the License as it pertained to the '771 patent. MedImmune, Inc., thereafter paid royalties to Celltech R&D Limited for its manufacture and sales of Synagis®.

17. On or around December 22, 2010, MedImmune, Inc., sent notice to Celltech R&D Limited disclosing its intention to terminate the License. MedImmune, Inc., then discontinued royalty payments as of January 22, 2011, thirty (30) days after the termination notice. Thus, as of January 23, 2011, Defendant MedImmune and/or its predecessors in interest were no longer licensed under the '771 patent.

COUNT FOR PATENT INFRINGEMENT

18. UCB incorporates each of the preceding Paragraphs 1 through 17 as if fully set forth herein.

19. Synagis® comprises a humanized antibody with affinity for RSV antigen, in the composite heavy chain of which, according to the Kabat numbering system, at least residues 26-35, 50-58, and 95-102 in the complimentary determining regions (CDRs), and at least residues 48, 49, 71, 73, 76, 78, 88, and 91 in the framework regions, are non-human donor residues.

20. MedImmune's commercial manufacture, use, offer to sell, or sale of palivizumab within the United States, or importation of palivizumab into the United States, during the term of the '771 patent, infringes, contributes to the infringement of, and/or induces the

infringement of the '771 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). MedImmune infringes or aids in the infringement of at least claim 1 of the '771 patent.

21. Upon information and belief, MedImmune has acted with full knowledge of the '771 patent and its claims without a reasonable basis for believing that it would not be liable for infringement of the '771 patent. Notwithstanding this knowledge, MedImmune has infringed the '771 patent since at least January 23, 2011, and continues to infringe the '771 patent through its commercial manufacture, use, offer to sell, sale, and/or importation of palivizumab.

22. Due to MedImmune's knowledgeable and willful infringement, UCB is entitled to treble damages under 35 U.S.C. § 284.

23. UCB is entitled to a finding that this case is exceptional and to an award of attorney's fees under 35 U.S.C. §285.

PRAYER FOR RELIEF

WHEREFORE, plaintiff UCB BioPharma SPRL prays for a judgment in its favor and against defendant MedImmune, LLC, and respectfully requests the following relief:

A. A judgment that MedImmune, LLC has infringed one or more claims of the '771 patent under 35 U.S.C. § 271, through the commercial manufacture, use, offer to sell, or sale in the United States, and/or importation or distribution into the United States, of palivizumab;

B. A judgment that MedImmune, LLC's continued commercial manufacture, use, offer to sell, or sale in the United States and/or importation or distribution into the United States of palivizumab would constitute infringement of the '771 patent pursuant to 35 U.S.C. § 271;

C. An award of damages, in an amount to be ascertained at trial, for MedImmune, LLC's past and continued infringement of claims of the '771 patent;

- D. A judgment that MedImmune, LLC's infringement is and has been willful;
- E. A trebling of all damages pursuant to 35 U.S.C. § 284;
- F. A judgment that this is an exceptional case and an award of reasonable attorney's fees pursuant to 35 U.S.C. § 285;
- G. Costs, expenses, and pre-judgment interest; and
- H. Such other relief as the Court deems just and proper.

Respectfully submitted,

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